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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 10/001,439                  | 10/25/2001  | Bill H. McAnalley    | 013258.0294         | 2421             |
| 27683                       | 7590        | 10/05/2007           | EXAMINER            |                  |
| HAYNES AND BOONE, LLP       |             |                      | HOFFMAN, SUSAN COE  |                  |
| 901 MAIN STREET, SUITE 3100 |             |                      | ART UNIT            | PAPER NUMBER     |
| DALLAS, TX 75202            |             |                      | 1655                |                  |
| MAIL DATE                   |             | DELIVERY MODE        |                     |                  |
| 10/05/2007                  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                         |  |
|------------------------------|--------------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>               | <b>Applicant(s)</b>     |  |
|                              | 10/001,439                           | MCANALLEY, BILL H.      |  |
|                              | <b>Examiner</b><br>Susan Coe Hoffman | <b>Art Unit</b><br>1655 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 18 July 2007 and 21 May 2007.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1,8-17,19 and 28-39 is/are pending in the application.  
4a) Of the above claim(s) 28-38 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1,8-17,19 and 39 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2007 has been entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claim 39 has been added.
3. Claims 1, 8-17, 19, and 28-39 are currently pending.
4. In the Office action of January 19, 2007, claims 28-38 were withdrawn as being non-elected by original presentation.
5. Claims 1-, 8-17, 19, and 39 are examined on the merits.

***Claim Rejections - 35 USC § 103***

6. Claims 1, 8-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donzis (US Pat. No. 5,576,015), Paul (US Pat. No. 5,531,989), Plaut (WO 97/05884) and McAnalley (WO 98/06418).

As discussed in the BPAI decision of September 22, 2006, Paul describes an immunoglobulin and fiber-containing composition for human gastrointestinal health. Paul describes that immunoglobulins from bovine colostrum have been shown to be an effective treatment for diarrhea due to pathogenic organisms. Column 2, lines 21-29. Paul also indicates

that immunoglobulin concentrates from milk contain active immunoglobulins that are capable of binding pathogenic organisms. Column 8, lines 10-16. Paul separates immunoglobulins from bovine milk and combines these purified immunoglobulins with lactoferrin, and dietary fibers such as inulin, guar gum and pectin. See e.g., column 3, line 58 - column 4, line 2 and formulation K, column 15. According to Paul (column 7, lines 13-15), "[r]ich sources of pectin include lemon and orange rinds..." Accordingly, Paul teaches citrus pectin. Paul acknowledges that soluble dietary fibers are found in many cereals. Column 6, lines 3-10. The composition of Paul may contain fructo- oligosaccharides, found in oats. See, claim 1. The composition of Paul may be manufactured in powder form. Column 13, line 38. Paul additionally acknowledges that infants develop gastroenteritis about the time they are weaned from breast milk and placed on formula. Column 1, lines 51-62. Thus, Paul would reasonably appear to suggest a powdered composition comprising lactoferrin, guar gum, citrus pectin and immunoglobulins derived from colostrum that is appropriate for use in infants to prevent gastroenteritis.

Plaut similarly describes infant formulas comprising colostrum (pasteurized milk) and lactoferrin. Plaut, page 3. Plaut indicates that antibodies from colostrum are known to protect children from infection by several gastrointestinal pathogens. Page 2. Plaut suggests that colostrum may be used or antibodies can be purified from milk and combined with lactoferrin as used as a formula additive. Page 6, lines 15-18. In the regard, Plaut discloses that the formula preferably includes colostrum. Plaut, page 5, lines 9-11. Finally, Donzis describes that glucan extracted from yeast cell walls is a potent stimulator of the immune system (Column 1, lines 20-21) and recommends that beta (1,3) glucans be incorporated as a nutritional supplement for a broad spectrum of animals and humans. Column 1, lines 52-67. Donzis indicates that beta glucan

strongly enhances resistance to diseases, both viral and bacterial, and enhances growth rate, survival rate and feed efficiency. Column 3, lines 15-27.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the colostrum of the infant formulas of Plaut comprising immunoglobulins, for the immunoglobulins derived from bovine colostrum of Paul into the composition of Paul, with the expectation that the colostrum incorporating natural immunoglobulins (Plaut) would function in a similar manner to the immunoglobulins derived from colostrum described in both Plaut and Paul. It would have been further obvious to incorporate the yeast cell wall beta-glucan, an insoluble fiber, of the nutritional supplement of Donzis, into the immunoglobulin and fiber nutritional supplement of Paul with the expected benefit of stimulating the immune system, enhancement of resistance to diseases, both viral and bacterial, and enhancement of growth rate, survival rate and feed efficiency, and promotion of gastrointestinal health. Donzis specifically states that yeast extract beta glucan can be combined with conventional nutritional materials to create a more supportive environment within the body to assist the primary killing action of conventional agents and thereby enhance significantly growth and survival. Column 5, lines 50-60.

Thus, Paul, Donzis, and Plaut together are considered to teach a composition comprising colostrum, beta-glucan, citrus pectin and saccharides. However, the references do not specifically teach including six or more "essential" saccharides in the composition. McAnalley teaches nutritional compositions comprising essential saccharides. The compositions can contain at least six essential saccharides and are derived from the same sources claimed by applicant (see pages 7 and 8). The reference teaches that these saccharide compositions are superior to other

types of saccharide dietary supplements because "by providing these essential saccharides, the mammal's body does not have to spend energy unnecessarily catabolizing these essential saccharides which allows for energy to be spent in other ways" such as by increasing the health and immune system of the patient (see page 7). Thus, McAnalley shows that it was known in the art at the time of the invention that using essential saccharides in the composition would produce better results than using non-essential saccharides. Therefore, an artisan of ordinary skill would then reasonably expect that the formulation of colostrum, beta-glucan, citrus pectin and taught by Donzis, Paul, and Plaut could be improved by substituting the saccharides for the essential saccharides of McAnalley. This reasonable expectation of success would motivate the artisan to modify the composition taught by Donzis, Paul, and Plaut to include essential saccharides as taught by McAnalley.

The references do not specifically teach adding citric acid, dextrose, magnesium stearate, silicon dioxide, and stearic acid to the composition. However, these ingredients are well known in the art to be added to pharmaceutical substances as part of a carrier system. Therefore, it is considered obvious to add these ingredients to the pharmaceutical composition taught by the references.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that

would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

7. Claims 1, 8-17, 19, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gohlke (US Pat. No. 6,258,383), Donzis (US Pat. No. 5,576,015) and McAnalley (WO 98/06418).

Gohlke teaches a composition that contains colostrum, lactoferrin, and citrus pectin. No other ingredients are required in the composition; thus, the composition is considered consistent essentially of these ingredients (see claims). Gohlke teaches that the composition is useful in preventing and inhibiting infection, stimulating the immune system, and promoting tissue healing and repair. The reference teaches incorporating the composition into the diet as a nutritional supplement to achieve these effects (see column 6).

Donzis teaches that glucan extracted from yeast cell walls is a potent stimulator of the immune system (Column 1, lines 20-21) and recommends that beta (1,3) glucans be incorporated as a nutritional supplement for a broad spectrum of animals and humans. Column 1, lines 52-67. Donzis indicates that beta glucan strongly enhances resistance to diseases, both viral and bacterial, and enhances growth rate, survival rate and feed efficiency. Column 3, lines 15-27. Donzis does not teach that any other ingredients are required.

McAnalley teaches using essential saccharides as a dietary supplement to promote good health. The composition allows the body to devote energy to healing and increasing the immune

system. The compositions can contain at least six essential saccharides and are derived from the same sources claimed by applicant (see pages 7 and 8). No ingredients other than the essential saccharides are required by the reference.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that improve health by increasing the immune system. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to improve health by increasing the immune system, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to improve health. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The references do not specifically teach adding citric acid, dextrose, magnesium stearate, silicon dioxide, and stearic acid to the composition. However, these ingredients are well known

in the art to be added to pharmaceutical substances as part of a carrier system. Therefore, it is considered obvious to add these ingredients to the pharmaceutical composition taught by the references.

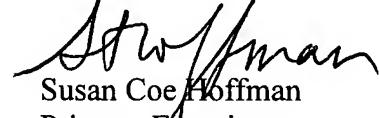
The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1655